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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.				
1940 DUKE STREET				
ALEXANDRIA, VA 22314				
EXAMINER				
MATTISON, LORI K				
ART UNIT		PAPER NUMBER		
1619				
NOTIFICATION DATE		DELIVERY MODE		
07/15/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com

oblonpat@oblon.com

jgardner@oblon.com

Office Action Summary

Application No.

10/553,791

Applicant(s)

SORE ET AL.

Examiner

LORI MATTISON

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/18/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/CD)
Paper No(s)/Mail Date 12/08/2009; 03/25/2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 13-32 are pending. Claims 1-12 are cancelled. Claim 32 is new. Upon further consideration claims 22, 23, 25 and 31 have been rejoined.
2. The claim listing filed 09/18/2009 is acknowledged.
Claims 13-32 remain pending and are examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Objections and rejections not recited in this action are withdrawn.
5. References not included with this Office action can be found in a prior action.

Election/Restrictions

The species election of thickener has been lifted insofar as xanthan gum and cellulose derivative (instant claim 21).

Instant claim 30 was rejoined in the office action mailed 06/26/2009. It is noted that the current claim listing has the status of claim 30 as "withdrawn."

Specification

The abstract of the disclosure remains objected to because it is not in an acceptable format. Applicant has submitted the face page of the international publication in lieu of an abstract. This face page contains additional text. The abstract of the disclosure must commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

The specification of the disclosure also remains objected to because the headings are not provided in the specification, making it difficult to determine which parts are present and their order.

Claim Objections

Instant claim 30 is objected to due to an informality. The claim status is incorrect. The current claim status should be previously presented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 29, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claims 27, 29, and 31 are indefinite because they fail to further limit the process of instant claim 13 from which they depend. Instant claim 27 recites, "The process as claimed in claim 13, which is a peeling process." It is observed that no additional method steps are recited and that there is no nexus made between the method steps of claim 13 and the "end-result" recited in claim 27 (i.e. peeling process). Instant claim 29 recites, "The process according to claim 13, wherein the skin is in need of treatment for at least one of wrinkles, fine lines, pigmentation marks, and acne scars." It is observed that no additional method steps are recited. Instant claim 31 recites, "The

process according to claim 13, wherein the skin is in need of treatment for blocked skin pores." It is observed that no additional method steps are recited.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 13-21, and 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,860,712 (Ferrari, 1975) as evidenced by the Merriam Webster dictionary definition for "several" and the Free Dictionary definition for "attenuate", the Macmillan Dictionary definition for "rinse," US Publication No. 2004/0197299 (Delattre, 2004), the *Medline Plus Medical Dictionary Definition* for desquamate, and DGNews as published at [://www.docguide.com/news/content.nsf/news/8525697700573E1885256CBB005272DF](http://www.docguide.com/news/content.nsf/news/8525697700573E1885256CBB005272DF) as published on 1/27/2003.

Claim Summary: The instant claims recite a method in which a composition of comprising at least 20% by weight urea in a physiologically acceptable medium is applied to the skin, remains in contact with the skin, and is removed by rinsing.

Ferrari teaches a method for treatment of acne or seborrhea (i.e. improving the visible and tactile irregularities on human skin; title) (instant claim 13). The composition is in the form of a soft gel that is left on the skin in a time ranging from several minutes to several hours and then is washed away either with or without soap or detergents (column 3, lines 30-40). As evidenced by the Macmillan dictionary definition for the word, "rinse," rinse means, "a quick wash, especially with flowing water." Thus, one of

ordinary skill in the art would recognize the teaching of Ferrari of a "quick wash without soap or detergents," as being rinsing with water.

With regard to the time component disclosed by Ferrari, as defined by the Merriam Webster Dictionary Definition for "several," "several" means more than two but less than many. Thus, the time range disclosed by Ferrari can be reasonably interpreted from 3 minutes to at least 3 hours. The adjustment of particular conventional working conditions (e.g. determining result effective amount of time in which to leave the composition on the face, ranging from several minutes to several hours as taught by Ferrari) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the ordinary artisan, with said artisan recognizing that the gel formulations are to be left on the skin for several minutes to several hours as taught by Ferrari.

Ferrari discloses that the amount of urea utilized in the composition ranges from 0.1 to 30 percent urea (column 1, lines 50-55). Thus, Ferrari is obvious over the claimed amount of urea where the claimed range of the amount of urea and the taught range of the amount of urea overlap.

Ferrari does not disclose inclusion of fats or oils. An examination of the Examples demonstrates that water, ethanol, and glycerol (all of which are hydrophilic) are the only solvents. Thus, the continuous phase is an aqueous phase.

Ferrari discloses and embodies inclusion of the excipient, glycerol (i.e. a polyol having 1-3 carbons) and ethanol in his compositions (column 2, lines 15-25; Formulation 1- column 4, lines 60-end; column 2, lines 1-5).

For formation of his gels, Ferrari discloses the use of carboxypolyethylene (CARBOPOL®) and methylcellulose (i.e. a cellulose derivative; column 2, lines 15-25; Formulation 7-column 6, lines 20-30).

With regard to instant claim 24, it is noted that the word "attenuate" means to "rarefy" as evidenced by the Free Dictionary. Ferrari discloses that his composition treats acne by removing sebum, which comprises triglycerides (column 1, lines 45-55; column 1, lines 15-25). These triglycerides are hydrolyzed by bacteria to produce free fatty acids which irritate the pilosebaceous canals to produce lesions such as comedones (i.e. acne), papules, pustules, nodules and cysts (column 1, lines 15-25). Thus, by treating acne by preventing/reducing its occurrence by removing the sebum from skin (column 1, lines 45-35), Ferrari is rarefying or "attenuating" the presence of acnes scars on the skin.

Ferrari discloses that the sebaceous glands (which develop comedones/acne) are located on the face and back (column 1, lines 10-20). It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to have modified Ferrari's composition by applying it to the face and the back because Ferrari's composition is meant to treat acne and acne occurs on the face and the back as taught by Ferrari.

With regard to the process being a peeling process, one of ordinary skill in the art would recognize the process as being a peeling process as the composition utilized in the composition taught by Ferrari comprises urea, which is a desquamation agent as evidenced by Delattre (page 5, paragraphs 81-84). As evidenced by the Medical

Dictionary definition of "desquamate," "desquamate" means to peel off in the form of scales. Thus, one of ordinary skill in the art would recognize that the desquamating properties results in the peeling off of at least one layer of epidermis cells resulting to get the "scale" pattern of cell removal. One of ordinary skill in the art would also recognize that the process of washing without detergents or soaps (i.e. washing with water/rinsing) also mechanically removes a layer of dead cells from the face.

With regard to instant claims 25 and 31, in light of DGNEWS, an effective acne treatment needs to open pores and keep them open (page 1 of 4, paragraph 1). This indicates that acne lesions have closed or "blocked pores." Thus, Ferrari's acne treatment method, in which the composition is applied to skin unblocks or opens pores in skin with acne (i.e. skin which is in need of treatment for blocked pores)(Ferrari-column 3, lines 30-40). This is further supported by the evidentiary teaching of DGNews which indicates that urea is keratolytic which works synergistically with sulfur to open pores and keep them open (page 1 of 4, paragraph 1).

With regard to instant claim 29, Ferrari teaches that his composition is applied in a method to treat acne (title). One of ordinary skill in the art would recognize that scarring is a common complication resulting from acne and that the two conditions are frequently associated together as acne occurs during puberty (i.e. phase in human development which lasts for several years). Thus, scars from early acne coexist with acne occurring at later stages of puberty. Since Ferrari teaches that the increased secretory activity which leads to acne occurs during puberty (column 1, lines 10-25),

one of ordinary skill in the art would recognize that the method and composition taught by Ferrari are also practiced on skin which is in need of treatment for acne scars.

Claims 13-21 and 24- 32 are rejected under 35 U.S.C. 103(a) as being unpatentable Ferrari, as evidenced by the Merriam Webster dictionary definition for "several" and the Free Dictionary definition for "attenuate", the Macmillan Dictionary definition for "rinse," Delattre, the *Medline Plus Medical Dictionary Definition* for desquamate, and DGNews, in view of US Patent No. 5,593,680 (Bara, 1997).

Claim Summary: The first composition comprises at least one thickener that is xanthan gum (instant claim 21).

The rejection of claims 13-21, and 24-32 under 35 USC 103(a) are addressed above. Ferrari discloses use of Carbopol and methylcellulose derivatives for use as excipients which gel and thicken Ferrari's gel composition (i.e. a cellulose derivative; column 2, lines 15-25; Formulation 7-column 6, lines 20-30).

Ferrari does not teach that the thickener is xanthan gum (the elected species) as set forth by instant claim 21.

Bara teaches a cosmetic or dermatopharmaceutical composition which is in the form of an aqueous gel (abstract). Bara teaches that the gelling agents used to gel the composition include xanthan gum and CARBOPOL®

With regard to instant claim 21, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have substituted the CARBOPOL® gelling agent taught by Ferrari for use in his gel with xanthan gum

because CARBOPOL® and xanthan gum are both suitable gelling agents used in topical gels as taught by Bara (column 3, lines 10-30). Thus, one of ordinary skill in the art would have a reasonable expectation in substituting xanthan gum for CARBOPOL® in topical gels.

Claims 13-21, and 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari as evidenced by the Merriam Webster dictionary definition for "several," Free Dictionary definition for "attenuate", the Macmillan Dictionary definition for "rinse," Delattre, the *Medline Plus Medical Dictionary Definition* for desquamate, and DGNews, in view of Skinterra Acne Solution as published at [://www.skinterra.com/acne/acne_solution.php](http://www.skinterra.com/acne/acne_solution.php) on 1/31/2001, Focus Area as published at [://www.infomat.net/1/focus/foci/eucerin/faqs.asp](http://www.infomat.net/1/focus/foci/eucerin/faqs.asp) on 3/31/2002, and Eucerin published at [://www.boots.com/en/Eucerin-Dry-Skin-Replenishing-Face-Cream-Night-5-Urea-with-Lactate-50ml_41614/](http://www.boots.com/en/Eucerin-Dry-Skin-Replenishing-Face-Cream-Night-5-Urea-with-Lactate-50ml_41614/) on 10/01/2002.

Claim Summary: The method comprises the step of applying a third composition to the skin which comprises 0.5%-10% by weight urea in a physiologically acceptable medium, after removing the first composition.

The rejection of claims 13-21, and 24-32 under 35 USC 103(a) is discussed above. Ferrari teaches removal of the compositions of his invention by washing them away either with or without soap or detergents (column 3, lines 30-40).

Neither Ferrari nor Bara teach application of a third composition to the skin which comprises from 0.5 to 10% by weight urea in a physiological acceptable medium after removing the first composition.

Skinterra teaches use of a water-based hydrating moisturizer daily for drier skin types prone to acne (page 2, paragraph 2).

Focus area teaches use of Eucerin Dry Skin Relief Night Renewal Face Cream which comprises 5% urea (page 2 of 6; Question 8). Focus Area teaches that urea is a natural moisturizing factor (page 4 of 6). Focus area teaches that urea rehydrates the epidermis (page 5 of 6, question 20). Thus, Eucerin Dry Skin Relief Night cream is a hydrating moisturizer.

Eucerin teaches that Eucerin Dry Skin Relief Night Renewal Face Cream is water based (i.e. the package lists the ingredient in non-alphabetical order; aqua/water is the first ingredient, indicating that it is the reagent present in the greatest quantity).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have modified the steps of the method taught by Ferrari by apply Eucerin Dry Skin Relief Night Renewal Face Cream (i.e. a composition which comprises 5% urea in a physiologically acceptable water base) subsequent to removal of Ferrari's acne gel because Skinterra teaches dry skin may still suffer from acne and that water-based hydrating moisturizers should be applied daily (page 2, paragraph 2). The skilled artisan would have been motivated to do so in order to treat dry skin which also has acne. The skilled artisan would have had an expectation of

success based upon Skinterra's teachings that water-based moisturizers may be used to rehydrate the skin.

Claims 13-22, and 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari, as evidenced by the Merriam Webster dictionary definition for "several" and the Free Dictionary definition for "attenuate", the Macmillan Dictionary definition for "rinse," Delattre, the *Medline Plus Medical Dictionary Definition* for desquamate, and DGNews, in view of Rosula Cleanser published at <http://www.empr.com/rosula-cleanser/acne/drug/4291/> on 2/1/2001.

Claim Summary: The process further comprises the step of applying a composition to the skin, which comprises from 0.5% to 10% by weight urea in a physiologically acceptable medium, before applying the first composition to skin.

The rejection of claims 13-21, and 24-32 under 35 USC 103(a) is discussed above. Ferrari teaches that an effective agent for relieving the conditions of acne is one which will effectively remove the sebum, fatty acids, and keratin from the skin and comedones (column 1, lines 28-30). Superficial sebum is removed with skin cleansing agents such as soap or medicated detergents containing the antibacterial hexachlorophene (column 1, lines 30-40).

Neither Ferrari nor Bara teach application of a composition comprising 0.5 to 10% by weight urea in a physiologically acceptable medium, before applying the first composition to the skin.

Acne kit teaches application of acne treatment cleansers before application of moisturizers and other acne treatments (page 1 of 2, paragraph 2- page 2 of 2, paragraphs 1 and 2). Acne kit teaches that cleansers cleanse the skin (page 1 of 2, paragraph 2).

Rosula Cleanser teaches application of Rosula cleanser 1-2 times daily for the treatment for acne vulgaris (page 4 of 11, lines 6-9). Rosula cleanser contains 10% urea (page 3 of 11, line 10).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have modified the steps of the method taught by Ferrari by applying Rosula Cleanser (a composition comprising 10 % urea in the physiologically acceptable cleanser medium) prior to applying Ferrari's composition because Ferrari acknowledges that skin is cleansed with detergents while Acne kit teaches that acne cleansers are applied prior to application of other moisturizers or other treatments. Rosula Cleanser is a cleanser specifically designed for the daily treatment of acne. The skilled artisan would have been motivated to do so in order to cleanse skin and treat acne as taught by Acne kit and Rosula cleanser. The skilled artisan would have had an expectation of success due to Rosula Cleanser that it is a treatment for acne.

Response to Arguments

In the traverse of the rejection of claims 13-16, 20,21, 26, 27 and 30 under 35 USC 103(a) over Davis, Herb, Brun, Bui-Bertrand, and Franklin; the rejection of claims

24 and 29 over Davis, Herb, Brun, Bui-Betrand, Franklin, and Sine; the rejection of claims 17-19 over Davis, Herb, Brun, Bui-Betrand, Franklin, Sine, and Juliano; and claim 28 over Davis, Herb, Brun, Bui-Betrand, Franklin and Buck, Applicant alleges that the Davis teaches that 0-25% nonliquid organic material are taught for use in Davis's composition (Reply, page 8, last paragraph). Applicant alleges that urea does not meet this criteria (Reply, page 9, first paragraph).

Applicant's traverse is moot in light of the new grounds of rejections above. The rejections of claims 13-16, 20,21, 26, 27 and 30 under 35 USC 103(a) over Davis, Herb, Brun, Bui-Betrand, and Franklin; the rejection of claims 24 and 29 over Davis, Herb, Brun, Bui-Betrand, Franklin, and Sine; the rejection of claims 17-19 over Davis, Herb, Brun, Bui-Betrand, Franklin, Sine, and Juliano; and claim 28 over Davis, Herb, Brun, Bui-Betrand, Franklin and Buck, are withdrawn.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LORI MATTISON whose telephone number is (571)270-5866. The examiner can normally be reached on 8am-6pm (Monday-Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LORI MATTISON/
Examiner, Art Unit 1619

/Anne Marie Grunberg/
Supervisory Patent Examiner, Art Unit 1661